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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/645,863	08/20/2003	Jonathan C. Heller	29191-707	7685

21971 7590 06/15/2005

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EXAMINER

DEJONG, ERIC S

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 06/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/645,863

Applicant(s)

HELLER ET AL.

Examiner

Eric S. DeJong

Art Unit

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 May 2005.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-15,17-27 and 29-43 is/are pending in the application.
- 4a) Of the above claim(s) 4-6,11-13,21,32-37,39,40 and 43 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3,7-10,14,15,17-20,22-27,29-31,38,41 and 42 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1,3-15,17-27 and 29-43 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED OFFICE ACTION

Acknowledgments

Applicants' arguments, filed 16 May 2005, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

The response filed by applicants on 16 May 2005 containing arguments directed to the previous Office action, mailed 19 April 2005, and an amended set of claims is acknowledged. The amended set of claims replaces all previous versions of the claims.

Claims 2, 16, and 28 are canceled. Claims 4-6, 11-13, 21, 32-37, 39, 40, and 43 are withdrawn from consideration. Claims 1, 3, 7-10, 14, 15, 17-20, 22-27, 29-31, 38, 41, and 42 are currently under examination.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1, 3, 7-10, 14, 15, 17-20, 22-27, 29-31, 38, 41, and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Olek et al. in view Fouillet et al. This rejection is maintained and reiterated from the previous Office action and necessitated by amendments to the instant claims.

Applicants assert that the withdrawal of the previous 102(a) rejections on the Olek et al. was on the basis that the reference fails to disclose the limitations of "without regard to a specific identity of at least some of said mass spectral components", "the identity of a plurality of said 15 markers is not known", and "in a computer system identifying the differences in case samples and control samples using said plurality of said more than 15 markers." The examiner does not agree with this assertion. As recited on page 11, lines 12-14 in a previous Office action, mailed 26 January 2005, Olek et al. does not fairly teach the limitation of using a mass spectroscopy platform preceded by a step of preparing samples on a microfluidics device. Amended claim 1 is now drawn to the use of a disposable microfluidics device which Olek et al. does not fairly teach and thus supports the withdrawal of the previous 102(a) rejection on the basis of the Olek et al. reference.

Applicants further assert that Olek et al. fails to disclose the limitations of "without regards to a specific identity of said more than 15 markers is not known" and "from blood samples of patients, in a computer system identifying the differences in case samples and control samples using said more than 15 markers wherein the specific identity of said more than 15 markers is not known". In regards to the limitation drawn to the specific identity of markers, the previous Office action, Chambers et al. was relied upon as a supporting document exemplifying the mass spectroscopic techniques applicable to the disclosed methodology and systems, as cited in Olek et al. Therefore an argument directed to Olek et al. rather than the supporting of Chambers et al. is found non-convincing. Contrary to applicants assertion that Olek et al. fails to teach the

limitation drawn to specific markers from blood samples, Olek et al. clearly sets embodiments of the disclosed methods and systems wherein the biological samples under investigation are derived from blood. See Olek et al., paragraph 0065.

Applicants further argues that neither Fouillet et al. nor Chambers et al. resolves the deficiency wherein the specific identity of some mass spectral components are not known. According to the applicants arguments, the teachings of Chambers et al., as cited in the previous Office action mailed 19 April 2005, clearly indicate that unidentified mass spectral components were utilized during the procedures even though some or all were later specifically identified. Amended claims 1 and 17-20 recite the use of markers wherein the specific identity of some markers is not known, however there is no constraint cited in the instant claims as to how any unknown marker or set of unknown markers are to be used in the disclosed invention. As such, the arguments presented by applicants are found non-convincing as the disclosed examples provided by Chambers et al., as admitted by applicants, clearly disclose the use of at least some unidentified markers in the disclosed mass spectroscopic techniques.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric S. DeJong whose telephone number is (571) 272-6099. The examiner can normally be reached on 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, Ph.D. can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instrument Examiner, Tina Plunkett, whose telephone number is (571) 272-0549.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center at (800) 786-9199.

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Ardin H. Marschel 6/13/05
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SUPERVISORY PATENT EXAMINER